REMARKS

The Applicant would like to thank the Examiner for the time extended for the courtesy of the office interview, conducted on November 29, 2005, in which agreement with respect to the claims was reached.

Claims 1, 4, 5, 7, 8, 13-17, 21, 22, 24, 27, 28, 30-32, 34, 37, 39, 41, 42, 44, and 47 have been amended in this response. Claims 46 and 49 have been canceled. New Claims 51-86 have been added. Thus, Claims 1-45, 47, 48, and 50-86 are currently pending for examination. No new matter is believed to be added by this amendment. In addition, unless a passage of an amendment is specifically discussed below in connection with one or more cited references, Applicant respectfully submit that the remarks accompanying this amendment should be constructed as being submitted merely to clarify the invention rather than as a limitation submitted to overcome a cited reference.

Applicant has amended Claims 4, 5, 7, 8, 13-16, 21, 22, 24, 27, 28, 30, 31, 37, 39, 41 and 42 to replace "constructed and arranged" language in an effort to further clarify the invention by the Applicant.

Claim Rejections under 35 U.S.C. §102(b)

Independent Claims 1, 17, 44, and 47 were rejected as being anticipated by United States Patent No. 4,521,210 to Wong. In response, Applicant would note that anticipation requires that each and every element as set forth in the claim must be found, either expressly or inherently described, in a single art reference. *See In re Robertson*, 49 USPQ2d, 1949, 1950-51 (Fed. Cir. 1999).[1]

1 The Federal Circuit has held that "[a] claim is anticipated only if each and every element *as set forth in the claim* is

Applicant respectfully traverses these rejections and respectfully requests that, in accord with the agreement reached in the office interview, the Examiner reconsider and withdraw the rejections of independent Claims 1, 17, 44, and 47, as currently amended. The independent Claims 1, 17, 44, and 47 have been amended to clarify the present invention by emphasizing that the elongate body of the implant is configured to position at least a portion of the insertion head and the first end of a conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision. Differences exist between the present invention, as claimed in the currently amended independent Claims 1, 17, 44, and 47 and the invention disclosed and taught by Wong.

As currently amended, independent Claims 1, 17, 44, and 47 read as follows:

1. An ophthalmic shunt implantable in an eye, comprising:

an elongate body having a forward end, a spaced back end, and an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the body having a substantially fusiform cross-sectional shape, the forward end and the insertion head of said body further defining a shoulder surface; and

a conduit having a first end defined on a portion of the top surface of said insertion head and extending through said body from the forward end to the back end thereof, the first end being spaced from the shearing edge and the shoulder surface of said body,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing

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found, either expressly or inherently described, in a single prior art reference." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (quoting *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed. Cir. 1983)) (emphasis in original).

edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

17. An ophthalmic shunt implantable in an eye, comprising:

a thin elongate body of a biocompatible material, the body having a forward end, a spaced back end, and a substantially fusiform cross-sectional shape, said body further comprising an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the shearing edge having a substantially arcuate shape, the forward end and the insertion head of said body further defining a shoulder surface; and

a conduit defined on a portion of the top surface of said insertion head and extending through said body from the forward end to the back end thereof, the conduit having a first end that is spaced from the shearing edge,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

44. A method for lowering eye pressure in an eye, comprising:

a. making a first incision in and through the conjunctiva and the sclera at a position posterior to the limbus;

b. providing a biocompatible ophthalmic shunt comprising:

i. an elongate body having a forward end, a spaced back end, and an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the

forward end and the insertion head of said body defining a shoulder surface; and

ii. a conduit having a first end defined on a portion of the top surface of said insertion head and extending through said body from the forward end to the back end thereof, the first end being spaced from the shearing edge and the shoulder surface of said body, wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision;

c. grasping a portion of the elongate body of the shunt;

d. disposing the insertion head of the shunt in and through the first incision and into the supracilliary space of the eye;

e. inserting at least a portion of the shearing edge of the insertion head of the shunt into and through the anterior chamber angle and into the anterior chamber of the eye so that the first end of the conduit is in fluid communication with the anterior chamber;

f. forcing the insertion head anteriorally to seat the shoulder surface of the implant adjacent an interior surface of the supraciliary space of the eye; and

g. suturing the first incision closed.

47. A method for treating glaucoma in an eye, comprising:

a. providing a biocompatible ophthalmic shunt comprising:

i. a thin elongate body of a biocompatible material, the body having a forward end, a spaced back end, and a substantially fusiform cross-sectional shape, said body further comprising an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the shearing edge having

a substantially arcuate shape, the forward end and the insertion head of said body defining a shoulder surface; and

ii. a conduit defined on a portion of the top surface of said insertion head and extending through said body from the forward end to the back end thereof, the conduit having a first end that is spaced from the shearing edge and the shoulder surface of said body, wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision;

b. inserting at least a portion of the shearing edge of the insertion head of the shunt into and through the anterior chamber angle and into the anterior chamber of the eye;

c. disposing the first end of the conduit into fluid communication with the anterior chamber of the eye;

d. introducing the insertion head anteriorally to seat the shoulder surface of the implant adjacent an interior surface of the supraciliary space of the eye;

e. disposing the back end of the elongate body of the shunt into the suprachoroidal space of the eye so that a second end of the conduit is in fluid communication with the suprachoroidal space; and

f. securing the shunt to the eye by suturing a portion of the elongate body to the eye.

Turning now to Wong disclosure, an eye implant device is taught that has surface channels extending its length to conduct fluid from the anterior chamber of the eye to the suprachoroidal space of the eye. There is no teaching of positioning the implant against the formed incision to seal the incision. Accordingly, Wong does not meet the standard required for anticipation. Consequently, the Examiner would be fully justified to reconsider and to withdraw

the rejections to the amended Claims 1, 17, 44 and 47. Accordingly, the claims dependent upon independent Claims 1, 17, 44 and 47 are also allowable over the cited art.

Further, turning now to the new independent Claims 54, 65 and 76, differences exist between the invention disclosed and taught by Wong and the present invention, as claimed in the new independent Claims 54, 65 and 76, which read as follows:

54. An ophthalmic shunt implantable in an eye, comprising:

an elongate body having a forward end, a spaced back end, and an insertion head extending from the forward end of the elongate body, the insertion head defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the forward end and the insertion head of said body further defining a shoulder surface; and

a conduit having a first end defined on a portion of the insertion head and extending through said body from the forward end to the back end thereof, the first end of the conduit being spaced from the shearing edge and the shoulder surface of said body,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

65. An ophthalmic shunt implantable in an eye, comprising:

an elongate body of a biocompatible material, the body having a forward end, a spaced back end, said body further comprising an insertion head extending from the forward end of the elongate body, the insertion head defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the shearing edge having a substantially arcuate shape, the forward end and the insertion head of said body further defining a shoulder surface; and

a conduit defined on a portion of the insertion head and extending through said body from the forward end to the back end thereof, the conduit having a first end that is spaced from the shearing edge,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the conduit through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

76. An ophthalmic shunt implantable in an eye, comprising:

an elongate body of biocompatible material, the body having a longitudinal axis, a forward end, a spaced back end, the body further comprising an insertion head extending from the forward end of the elongate body, the insertion head defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the body defining a longitudinally extending bore, a proximal end of the bore defined in the forward end of the body, the proximal end positioned adjacent a portion of a surface of the insertion head, the forward end and the insertion head of said body further defining a shoulder surface; and

a tube of biocompatible material, the tube having a first end and a spaced second end, at least a portion of the tube positioned within the bore of said body such that the second end of the tube is adjacent a distal end of the bore of said body and such that the first end of the tube extends through the proximal end of the bore and overlies a portion of the surface of the insertion head, the first end of the tube being spaced from the shearing edge and the shoulder surface of said body,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the tube through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

As noted above, Wong fails to teach positioning of the implant against a formed incision to seal the incision. Consequently, the independent Claims 54, 65 and 76 should be in a condition for allowance. Accordingly, the claims dependent upon independent Claims 54, 65 and 76 are also allowable over the cited art.

Claim Rejections under 35 U.S.C. §103(a)

Applicant respectfully traverses the rejections of independent Claims 32 and 34 under 35 U.S.C. §103(a) and respectfully requests that, in accord with the agreement reached in the office interview, the Examiner reconsider and withdraw the rejections of independent Claims 32 and 34, as currently amended.

Independent Claim 32 was rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of United States Patent No. 5,476,445 to Baerveldt et al. As noted above, Wong teaches an eye implant device that has surface channels extending its length to conduct fluid from the anterior chamber of the eye to the suprachoroidal space of the eye. There is no teaching of positioning the implant against the formed incision to seal the incision. Baerveldt teaches the use of a drainage tube for removing excess fluid from the eye.

As currently amended, Claim 32 reads as follows:

32. An ophthalmic shunt implantable in an eye, comprising:

a thin elongate body of biocompatible material, the body having a longitudinal axis, a forward end, a spaced back end, and a substantially fusiform cross-sectional shape, the body further comprising an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the body defining a longitudinally extending bore, a proximal end of the bore defined in the forward end of the

body, the proximal end positioned adjacent a portion of the top surface of the insertion head, the forward end and the insertion head of said body further defining a shoulder surface; and

a tube of biocompatible material, the tube having a first end and a spaced second end, at least a portion of the tube positioned within the bore of said body such that the second end of the tube is adjacent a distal end of the bore of said body and such that the first end of the tube extends through the proximal end of the bore and overlies a portion of the top surface of the insertion head, the first end of the tube being spaced from the shearing edge and the shoulder surface of said body,

wherein the elongate body is configured to position at least a portion of the insertion head and the first end of the tube through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

Similarly, independent Claim 34 was rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of United States Patent No. 5,599,330 to Rainin. As noted above, Wong teaches an eye implant device that has surface channels extending its length to conduct fluid from the anterior chamber of the eye to the suprachoroidal space of the eye. There is no teaching of positioning the implant against the formed incision to seal the incision. Rainin discloses the use of a wicking member.

As currently amended, Claim 34 reads as follows:

34. An ophthalmic shunt implantable in an eye, comprising:

a thin elongate body of biocompatible material, the body having a longitudinal axis, an upper surface, a forward end, a spaced back end, and an insertion head extending from the forward end of the elongate body, the insertion head having a top surface and

defining a shearing edge constructed and arranged for cutting eye tissue engaged thereby, the upper surface of the body defining a longitudinally extending slit, the forward end and the insertion head of said body further defining a shoulder surface; and

a wicking member having an inlet end and an outlet end, the wicking member configured to regulate the flow of aqueous humor from the inlet end to the outlet end and for positioning within at least a portion of the slit of said body and overlying a portion of the top surface of the insertion head, the inlet end of the wicking member being spaced from the shearing edge of said body,

wherein the elongate body is configured to position at least a portion of the insertion head and the inlet end of the wicking member through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye and to seat at least a portion of the shoulder surface of the insertion head against the incision to seal the incision.

In contrast to the combination of the Wong and Baerveldt disclosures, the invention set forth in independent Claim 32, as currently amended, is for an eye implant in which at least a portion of the insertion head of the elongate body and the first end of a tube is positioned through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye. Further, at least a portion of the shoulder surface of the insertion head is seated against the incision to seal the incision. Accordingly, one skilled in the art would not have been motivated to modify Wong and Baerveldt to arrive at the claimed invention because there is no teaching to make the modification. Nor is there any suggestion of such a design in the Wong or Baerveldt disclosures. Thus, a modification to sealing seat a portion of the elongate body of the implant against the incision would require hindsight reasoning, which the Federal Circuit has explicitly rejected. *See In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992) ("Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or

'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious.").

Similarly, in contrast to the Wong and Rainin disclosures, the invention set forth in independent Claim 34, as currently amended, is for an eye implant in which at least a portion of the insertion head of the elongate body and the first end of the wicking member is inserted through an incision formed by the shearing edge of the insertion head and into fluid communication with the anterior chamber of the eye. At least a portion of the shoulder surface of the insertion head of the body is seated against the incision to seal the incision. Accordingly, one skilled in the art would not have been motivated to modify Wong and Rainin to arrive at the claimed invention because there is no teaching or suggestion of such a design or modification in the Wong or Rainin disclosures. Thus, a modification to seat a portion of the elongate body of the implant against the incision to seal the incision would require hindsight reasoning.

Furthermore, seating a portion of the elongate body of the implant against the incision to seal the incision would prevent the Wong apparatus from being used as designed (as the surface channels of Wong would be blocked), which also undermines an obviousness rejection. *See In re Fritich*, 972 F.2d 1260, 1265 n.12, 23 U.S.P.Q.2d 1780, 1783 n.12 (Fed. Cir. 1992) ("This court has previously found a proposed modification inappropriate for an obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purpose.") (citing *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984)); *Schneider (Europe) AG v. Scimed Life Sys., Inc.*, 852 F. Supp. 813 (D. Minn. 1994) ("Where obviousness is based upon a modification of a reference that destroys the intended purpose or function disclosed in a reference, there is no motivation for engaging in the modification.") (citing *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984)).

Therefore, Claims 32 and 34, as amended, would not be rendered obvious by the cited combination of references. Accordingly, the claims dependent upon independent Claims 32 and 34 are also allowable over the cited art. *See In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.").

Therefore, Applicant respectively requests allowance of all the outstanding claims. The Examiner is invited and encouraged to contact directly the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Credit Card Authorization form PTO-2038 in the amount of $1,100.00 for new Claims 51-86 ($300.00 for 3 new independent claims and $800.00 for 36 new claims in excess of 20) is enclosed. No additional fees are believed to be due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 8, 2005.

Kean J. DeCarlo — Date 12/8/2005

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